

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 65D0662219	(X3) Date Survey Completed 07/15/2025
Name of Provider or Supplier Diagnostic Lab Services, Inc - Itc	Street Address, City, State 590 S Marine Corps Dr, Tamuning, GU	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Federal Surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a recertification survey on 7/14/2025 and 7/15/2025. The following standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: I. Based in review of the manufacturer's instructions, the laboratory's procedures, review of patient testing records, and interview with the technical supervisor #1, the laboratory failed to follow and document the conditions of transportation (temperature) of ferritin serum specimens when received into the laboratory according to their procedures in 2025 for 5 of 5 Saipan patients reviewed as evidenced by: 1.In review of manufacturer's instructions for ferritin states under specimen collection and preparation, "Serum, heparin, K3-ETDA plasma samples are 24 hours at 20-25 degrees, 7 days at 2-8 degree C, 12 months at -20 degrees +/- 5 degrees C". 2. In review of the laboratory's procedures Ferritin Cobas technical procedures states, "ambient stability 24 hours at 20-25 degrees C, refrigerated stability 7 days at 2-8 degrees C." 3. In review of the laboratory's patient testing records from Saipan, the laboratory did not document the conditions of transport (temperature) upon arrival of ferritin serum specimens for 2025. The laboratory did not have documentation that the specimens (2025) were transported at 2-8 degrees C. 4.The following ferritin patients were past the room temperature 24 hours specimen integrity: a. Patient YF49760525</p>

on 6/30/2025 was received 347.9 hours after collection with no documentation of transportation temperature conditions. b. Patient YF49764181 on 6/30/2025 was received 33 hours after collection with no documentation of transportation temperature conditions. c. Patient YF49979837 on 7/2/2025 was received 35.1 hours after collection with no documentation of transportation temperature conditions. d. Patient YF50402441 on 7/7/2025 was received 33.3 hours after collection with no documentation of transportation temperature conditions. e. Patient YF50750376 on 7/10/025 was received 32.7 hours after collection with no documentation of transportation temperature conditions. 5. In an interview with technical supervisor #1 at 0845 at 7-15-2025 he stated that he believed that everything coming in from outside facilities from Saipan were refrigerated when they switch to DHL a few years ago. 47107 II. Based on review of the laboratory's procedures, test volumes, direct observation, review of patient testing records, and interview with Technical Supervisor (TS)-1, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow and document the conditions of transportation (temperature) of Rapid Plasma Reagin (RPR) serum specimens when received in the laboratory according to their procedures in 2025 for 1 of 1 Saipan patients reviewed. Findings Included: 1. Review of the laboratory's procedures for RPR titled 'Diagnostic Laboratory Services, Inc. RPR G400.70.90' stated the following on page 1 of 6: "2.2 Stability: Serum is stable up to 5 days at 2-8 degrees Celsius. If more than 5 days, specimen should be frozen at -20 degrees Celsius or below." 2. Review of the laboratory's patient testing records showed an annual RPR test volume of 4,624. 3. In direct observation on July 15, 2025 at 2:44 PM, the following RPR patient sample(s) were observed shipped from Saipan and received by the laboratory all in one box labeled 'Room Temperature, Refrigerate & Frozen', with no mechanism in place to track shipping transport (temperature) conditions: a. Patient YF51108686, Gold-Top Serum Separator Tube (SST), with no documentation of transportation temperature conditions. 4. In review of the laboratory's patient testing records from Saipan, the laboratory did not document the condition of transport (temperature) upon arrival of RPR specimens for 2025. The laboratory did not have documentation that the specimens were transported at 2-8 degrees Celsius or at -20 degrees Celsius and colder. 5. In an interview at 2:45 PM in the laboratory, TS-1 stated and confirmed the observation that specimens received from Saipan and other facilities come together in one package, even if room temperature, refrigerated or frozen requirements for transport and/or storage, and the laboratory did not have a mechanism in place to track transport temperatures.

D5401

PROCEDURE MANUAL
 CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
 I. Based on direct observation, review of the laboratory's policy, temperature records, test volumes, and interview with the Technical Supervisor (TS)-2 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to document calculation of the average yearly room temperature where the Microscan Walkaway System 40Si was in use for 2 of 2 years (2024 and 2025). Findings Included: 1. In direct observation on 7/15/2025 at 10:39 AM in the microbiology

section, 1 Microscan Walkaway System 40Si was observed in use for ID and Antibiotic Susceptibility Testing (AST). 2. Review of the laboratory's policy titled, 'Diagnostic Laboratory Services, Inc. Microscan Walkaway System 40Si G401.90. EQP.01' stated the following annual temperature calculation requirement: "Store at 2-25 degrees Celsius, excursions permitted to 30 degrees Celsius. Average yearly temperature not to exceed 25 degrees Celsius. Transient temperature spikes are acceptable, as long as average storage temperature does not exceed 25 degrees Celsius." 3. Review of the microbiology section's room temperature records showed an acceptable range of 15 to 30 degrees Celsius, but no annual temperature average calculation completed by the laboratory in 2023 and 2024. 4. Review of the laboratory's test volumes in 2024 for the Microscan Walkaway System 40Si showed the following: a. Staph Sensi - 1,802 b. Gram Negative Sensi - 7,076 c. Enterococcus Sensi - 572 d. Pseudomonas Sensi - 383 5. In an interview on 7/15/2025 at 10:45 AM in the conference room, TS-2 confirmed that the laboratory did not follow their own policy to do an annual calculation of average recorded room temperature in the microbiology section (not to exceed 25 degrees Celsius) where the Microscan Walkaway System 40Si was in use. II. Based on direct observation, review of the manufacturer's instructions, laboratory policy, test volume records, and interview with the Technical Supervisor (TS)-2, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow its own policy for using a high intensity incandescent lamp for 1 of 1 test methodology (Becton Dickinson Macro-Vue Rapid Plasma Reagin Card Test). Findings Included: 1. In direct observation on 7/14/2025 at 3:19 PM in the laboratory, the Rapid Plasma Reagin (RPR) workbench had dim room lighting and did not have a high intensity incandescent lamp for RPR card test readouts. 2. Review of the manufacturer's instruction from Becton Dickinson (BD) for the Macro-Vue RPR Card Test 18 mm Circle Qualitative and Quantitative stated the following requirement: "Reading of Card Test Results: Read immediately following rotation in the "wet" state under a high intensity incandescent lamp or strong daylight." 2. Review of the laboratory's policy titled 'Diagnostic Laboratory Services, Inc. RPR G400.70.90' stated the following on page 3 of 6: "Immediately read macroscopically in the 'wet' state under a high intensity incandescent lamp". 3. Review of the laboratory's patient testing records showed an annual RPR test volume of 4,624. 4. In an interview on 7/14/2025 at 3:21 PM in the laboratory, TS-2 confirmed that an incandescent lamp was not utilized for RPR testing, in accordance with the laboratory's policy.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references.

(b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, lack of quality control records, and an interview with the technical supervisor (TS), the laboratory failed to include control procedures in three out of sixteen microscopic examinations performed by the laboratory. Findings Included: 1. A review of the following procedures on July 15, 2025, at 11:00 a.m. revealed that the below three procedures did not include control procedures for microscopic testing: a. Post-vasectomy Exam. b. Hanging Drop Test. c. Synovial Fluid Crystal Exam. 2. On July 15, 2025 at 11:30 am, the laboratory was unable to provide QC performed for the above tests. 3. In 2024, the following number of tests were performed for each test: a. Post vasectomy - 25 microscopic examinations. b. Synovial Fluid Crystal Exam - 32 microscopic examinations. 4. By interview, the TS confirmed the above findings on July 15, 2025, at 3:00 pm.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

I. Based on direct observation, manufacturer's instructions, and interview with the Technical Supervisor (TS)-2, according to the Centers for Medicare and Medicaid (CMS) 209 Form, the laboratory failed to follow the manufacturer's instructions for storage for 50 of 50 StatLab Medical Products 5mL Prefilled Containers with 3% Glutaraldehyde in Cacodylate Buffer. Findings Included: 1. In direct observation on 7/15/2025 at 9:25 AM in the laboratory, 50 containers (1 case) of StatLab Medical Products 5mL Prefilled Containers with 3% Glutaraldehyde in Cacodylate Buffer, Lot #228162, Manufacturer storage temperature requirements 2 to 10 degrees Celsius. 2. In an interview on 7/15/2025 at 9:30 AM in the laboratory, TS-2 confirmed the supplies improperly stored outside of the refrigerator, not in accordance with manufacturer instructions.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation, manufacturer's instructions, temperature records, and interview with Technical Supervisor (TS)-1, according to the Centers for Medicare and Medicaid (CMS) 209 Form, the laboratory failed to define, monitor and document the room temperature where 14 of 14 Beckman Coulter MicroScan PC45 boxes were stored. Findings Included: 1. In direct observation on 7/14/2025 at 12:57 PM, the following supplies were seen in storage in the hallway area without temperature monitoring or documentation: a. 14 Beckman Coulter MicroScan PC45 boxes, Ref #B1017-219, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. 2. Review of the laboratory's temperature records revealed no temperature ranges defined, monitored and documented in the hallway area of the laboratory where supplies/reagents were stored. 3. In an interview on 7/14/2025 at 1:00 PM, TS-1 confirmed the temperature was not defined, monitored and documented in the hallway area of the laboratory where the aforementioned reagents/supplies were stored. II. Based on direct observation, manufacturer's instructions, temperature records, and interview with Technical Supervisor (TS)-2, according to the Centers for Medicare and Medicaid (CMS) 209 Form, the laboratory failed to define the room temperature where three of three boxes of Beckman Coulter reagents/supplies were stored in the microbiology section. Findings Included: 1. In direct observation on 7/15/2025 at 9:25 AM, the following supplies were seen in use in the microbiology section: a. one Beckman Coulter MicroScan PC45 box, Ref# B1017-219, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. b. one Beckman Coulter MicroScan NUC102 box, Ref# C89644, Manufacturer storage temperature requirements 2 to 25 degrees Celsius. c. one Beckman Coulter MicroScan MicroScan PROMPT Inoculation System-D box, Ref# B1026-10D, Manufacturer storage temperature requirements 2 to 27 degrees Celsius. 2. Review of the laboratory's temperature records for the microbiology section revealed an acceptable room temperature range of 15 to 30 degrees Celsius. 3. In an interview on 7/15/2025 at 9:30 AM, TS-2 confirmed the laboratory's defined temperature for the microbiology section did not follow an acceptable range as defined by the manufacturer instructions of the aforementioned supplies/reagents in use.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, lack of stain (QC) records, and an interview with the technical supervisor (TS), the laboratory failed to document QC for each microscopic examination in hematology each day of use, for their intended reactivity from July 2023 to July 2025 (24 of 24 months). Findings include: 1. Review of laboratory procedures revealed that the following tests were performed with the use of Camco Quik Stain II (Buffered Differential Wright-Giemsa Stain): a. Synovial Fluid Examination. b. RBC Morphology. c. WBC Differential. d. Eosinophil count 2. On July 15, 2025 at 1:00 pm, review of stain QC records revealed, the laboratory did not document positive and negative intended reactivity for the Wright-Giemsa stain

used to stain slides for the above tests. 3. In 2024 the following number of tests were performed: a. Synovial Fluid Examination - 32. b. WBC Differential - 5299. 4. By interview, the TS confirmed the above findings on July 15, 2025, at 3:00 pm.

D5543

HEMATOLOGY

CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate.

This STANDARD is not met as evidenced by:

Based on the review of hematology test records, lack of documented quality control (QC) and an interview with the technical supervisor (TS), the laboratory failed to document QC for 124 of 124 microscopic complete semen analysis performed in 2024. Findings included: 1. The Semen Analysis, complete procedure 5. Quality control, 5.2 states, "A comparison of counts between both halves of the hemocytometer must be made". "The counts must match by 10%". 2. Review of laboratory records on July 15, 2025, revealed the laboratory did not document QC for complete semen analysis examinations performed. 3. In 2024, 124 semen specimens were analyzed on the hemocytometer. 4. By interview, the TS confirmed the above findings on July 15, 2025, at 3:00 pm.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, manufacturer instructions, temperature records, test volumes, and interview with the Technical Supervisor (TS)-1, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to have documentation of performing corrective action when the room temperature was documented outside the acceptable range for Rapid Plasma Reagin (RPR) testing for 10 of 93 working days reviewed from March 1, 2024 to July 15, 2025 (Random review). Findings Included: 1. A review of the manufacturer instructions stated the following for the Becton Dickinson (BD) Macro-Vue RPR Card Tests: "Immediate use of a refrigerated antigen may result in decreased sensitivity of the test. Therefore, upon removal from the refrigerator, allow the antigen to warm to room temperature (23 to 29 degrees Celsius) before use." 2. A review of the laboratory's policy titled 'Diagnostic Laboratory Services, Inc. RPR G400.70.90' stated the following on page 3 of 6: "Controls, RPR antigen suspension and test suspension should be at room temperature (23-29 degrees Celsius) when used." 3. Review of the laboratory's

temperature records on a Quality Control (QC) record document titled 'Diagnostic Laboratory Services Serology Department RPR QC Logsheet' revealed the following dates where temperatures were outside of the range defined by the laboratory's policy without any documentation of corrective action performed: a. March 17, 2025 - 20 degrees Celsius, AG Lot#4033530, Control Lot#4222044 b. April 7, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4222044 c. April 9, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4222044 d. April 11, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4222044 e. April 16, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4222044 f. April 18, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4222044 g. May 30, 2025 - 22 degrees Celsius, AG Lot#3305584, Control Lot#4316061 h. June 16, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4316061 i. June 20, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4316061 j. July 7, 2025 - 22 degrees Celsius, AG Lot#4033530, Control Lot#4316061 4. Review of the laboratory's patient testing records showed an annual RPR test volume of 4,624. 5. In an interview on 7/15 /2025 at 3:03 PM in the conference room, TS-1 confirmed that the laboratory failed to document corrective actions for RPR testing outside of the allowable temperature range for the aforementioned dates.

D6139

CLINICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1457(c)

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

This STANDARD is not met as evidenced by:
Based on a review of patient test reports and interview with the technical supervisor (TS), the clinical consultant failed to ensure reports included reference ranges for patient interpretation for body fluid microscopic examinations from July 2023 to July 2025 (24 of 24 months). Finding Included: 1. Based on a review of a sampling of body fluid microscopic examinations on July 15, 2025, at 2:00 pm, the patient's test report did not include reference ranges for RBC, WBC, neutrophils, lymphocytes, monocytes, eosinophils, and basophils for patients testing performed from July 2023 to July 2025. 2. The following number of body fluid examinations were performed in 2024: Body Fluid Profile - 125. CSP Profile - 75. 3. By interview, the TS confirmed on July 15, 2025, at 3:00 pm that test reports did not include reference ranges for body fluid examinations.